IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 11-704 (LPS)
	)	CONSOLIDATED
ACTAVIS SOUTH ATLANTIC LLC, et al.,	)	
	)	
Defendants.	)	

AVANIR'S OPENING CLAIM CONSTRUCTION BRIEF

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Dated: August 17, 2012

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I. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs Avanir Pharmaceuticals, Inc., Avanir Holding Company, and Center for Neurologic Study (collectively, "Avanir") submit this opening brief in support of their proposed constructions of the disputed terms of U.S. Patent Nos. RE38,115 ("the '115 patent," attached as Ex. A)[1] and 7,659,282 ("the '282 patent," attached as Ex. B) (collectively, "the patents-in-suit"). Avanir alleges that Defendants have infringed the patents-in-suit under 35 U.S.C. § 271 by filing Abbreviated New Drug Applications ("ANDAs") seeking the Food and Drug Administration's ("FDA's") permission to market generic versions of Avanir's Nuedexta® drug product prior to the expiration of the patents-in-suit. The parties submitted a Joint Claim Construction Chart on July 20, 2012. (D.I. 110.) A *Markman* hearing is scheduled for October 5, 2012.

II. SUMMARY OF ARGUMENT

There are two patents-in-suit. The '115 patent covers formulations containing dextromethorphan and quinidine, the active ingredients in Nuedexta®. The '282 patent covers methods of using dextromethorphan and quinidine to treat a neurological disorder known as pseudobulbar affect ("PBA").

There are two main claim construction disputes regarding the '115 patent. First, Defendants erroneously contend that the preamble of the asserted clams is a limitation. Because the preamble "a unit dosage formulation for treatment of chronic or intractable pain" is merely a statement of intended purpose, it cannot be a limitation. Thus, it does not need to be construed.

Second, Defendants erroneously propose that the following phrase must be construed as a whole:

> a combined dosage which renders the dextromethorphan therapeutically effective in substantially reducing chronic or intractable pain without causing unacceptable side effects.

[1] "Ex. __" herein refers to the exhibits to the Declaration of Daniel Wiesner.

This 21-word phrase, however, is not an individual claim term. Rather it is an amalgam of several separate terms, the majority of which have their plain and ordinary meanings and do not require construction. Indeed, the parties ***agree*** that "chronic pain" and "intractable pain" are the only terms within this phrase that require construction, as Defendants have ***refused to even discuss*** with Avanir the meanings of any other individual terms within this phrase. Therefore, Defendants should be precluded from arguing that the terms have anything other than their plain and ordinary meanings — as proposed by Avanir.

Instead of offering constructions for the individual terms, Defendants improperly attempt to import numeric limitations from examples in the specification into the claims and attribute those limitations to the phrase as a whole. This violates Federal Circuit law against reading limitations from the specification into claim terms. Thus, the individual terms "chronic pain" and "intractable pain" should be separately construed — as Defendants concede — and the remaining terms should not be construed because they have their plain and ordinary meanings.

The remaining disputes regarding the '115 patent concern the meanings of "a debrisoquin hydroxylase inhibitor," "chronic pain" and "intractable pain." For "a debrisoquin hydroxylase inhibitor," the patentee clearly and unambiguously disclaimed coverage of the compound "cimetidine" from the scope of the claims during prosecution. Defendants erroneously refuse to acknowledge this clear disavowal. For "chronic pain," the parties' constructions are similar except that Defendants improperly include examples from the specification in their proposed construction. For "intractable pain," the constructions offered by both parties are similar, but Avanir's construction is more consistent with the use of the term in the claims and in the specification. Accordingly, the Court should adopt Avanir's proposed constructions.

The parties only dispute two terms of the '282 patent. The first disputed term is the preamble of claim 1, "a method for treating pseudobulbar affect or emotional lability." The parties agree that this preamble is a limitation (because it provides antecedent basis for a subsequent claim). While Avanir's proposed construction is the patentee's lexicography, Defendants' proposed construction includes extraneous language that is not properly part of the definition of the term. Accordingly, the Court should adopt Avanir's proposed construction.

The second disputed term is "dextromethorphan in combination with quinidine." In the '282 patent, the claims and specification both refer to dextromethorphan "in combination" with quinidine in "combined doses" and in "separate doses." The parties appear to disagree over what it means to have separate doses "in combination." Avanir relies on the use of the term in the specification for its construction that the separate doses "in combination" must be administered "substantially simultaneously." Defendants improperly fail to include any temporal limitation in their construction, such that separate doses "in combination" could be administered days, or even weeks, apart. This not only defies the specification and logic, but also defeats the purpose of the invention. The Court should therefore adopt Avanir's proposed construction.

III. BACKGROUND

Avanir markets a combination dextromethorphan/quinidine product under the trade name Nuedexta®. Each Nuedexta® capsule contains 20 mg of dextromethorphan and 10 mg of quinidine and is administered once a day for a week, and then twice a day. Nuedexta® is the first and only treatment approved by the FDA for pseudobulbar affect ("PBA"). PBA is a neurological disorder characterized by intermittent spasmodic outbursts of emotion, such as involuntary and uncontrolled laughing or crying, at inappropriate times or in the absence of any particular provocation. (Ex. B at 1:39-44.) PBA occurs secondary to a variety of otherwise unrelated neurological conditions, including amyotrophic lateral sclerosis, also known as Lou

Gehrig's disease, multiple sclerosis, stroke and traumatic brain injury, but it is a distinct neurologic disorder which can be diagnosed separately from the underlying disease or injury. (*Id.* at 1:23-38.) It is estimated that nearly 2 million people suffer from PBA. The loss of emotional control caused by PBA is debilitating, causing patients to avoid normal work and social activities. (*Id.* at 1:52-2:3.)

The asserted claims of the '115 patent cover formulations of dextromethorphan combined with quinidine. The formulations claimed in the '115 patent contain sufficient quantities of dextromethorphan and quinidine to treat chronic or intractable pain. (Ex. A at 18:26-47.)

The '282 patent covers methods of treating PBA with dextromethorphan in combination with low doses of quinidine. (Ex. B at 78:2-34.) Specifically, the claims of the '282 patent require from about 20 mg/day to about 80 mg/day of dextromethorphan and from about 10 mg/day to less than about 30 mg/day of quinidine.

IV. LEGAL STANDARDS

Claim construction is an issue of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995)(en banc), *aff'd*, 517 U.S. 370 (1996). The Federal Circuit has explained that claim construction starts with the words of the claims. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003). Claim terms are deemed to be read "not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). If the patentee has specifically defined a claim term in the specification, that definition controls. *Id.* at 1316. When the patentee has not provided an explicit definition of a claim term, however, the words of a claim are generally given their plain and ordinary meaning to a person of ordinary skill in the art at the time of the invention. *Id.* at 1313; *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While the specification undoubtedly serves as a guide to claim construction, the Federal Circuit has repeatedly cautioned against importing limitations from the specification into the claims. *Phillips*, 415 F.3d at 1312. A court must also consider the prosecution history. Absent a clear and unmistakable disavowal of claim scope, however, the plain and ordinary meaning of the claim terms control. *Sorensen v. Int'l Trade Comm'n*, 427 F.3d 1375, 1378-79 (Fed. Cir. 2005). A court may also consider extrinsic evidence to the extent that such evidence is consistent with the intrinsic evidence. *See Phillips*, 415 F.3d at 1318.

V. ARGUMENT

A. The '115 Patent

The '115 patent is titled "Dextromethorphan And An Oxidase Inhibitor For Treating Intractable Conditions." A person of ordinary skill in the art with respect to the '115 patent is a pharmacologist having substantial experience with compositions of matter useful for preparing medicaments for the treatment of chronic or intractable pain. (Ex. A at 1:19-22.) Avanir is asserting claims 18-21. These claims cover pharmaceutical formulations containing the active ingredients dextromethorphan and quinidine. All of the disputed claim terms appear in claim 18, which states (with emphasis on the disputed claim terms):

> **A unit dosage formulation for treatment of chronic or intractable pain**, comprising: (a) dextromethorphan or a pharmaceutically acceptable salt thereof, and, (b) **a debrisoquin hydroxylase inhibitor**, in a combined form that is designed for oral ingestion by humans, wherein the dextromethorphan or salt thereof and the **debrisoquin hydroxylase inhibitor** are present at a combined dosage which renders the dextromethorphan therapeutically effective in substantially reducing **chronic or intractable pain**, without causing unacceptable side effects.

Claims 19-21 are dependent claims that incorporate all of the limitations of claim 18 plus additional limitations. The parties agree that the disputed claim terms in claim 18 will carry the same meanings when they appear in claims 19-21.

1. "A unit dosage formulation for treatment of chronic or intractable pain"

Avanir's Construction	Defendants' Construction
[The preamble is not a claim limitation; needs no construction]	A unit dosage formulation intended to treat chronic or intractable pain

The parties disagree on whether "A unit dosage formulation for treatment of chronic or intractable pain" requires construction. This language appears in the preamble of claim 18. Avanir's position is that this preamble is not a claim limitation and therefore does not need to be construed.

A claim's preamble generally does not limit the scope of the claim. *American Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010). The Federal Circuit has set forth certain exceptions to this general rule. *Id.* For example, the preamble limits the scope of the claim if: (i) "it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim"; (ii) it provides a necessary antecedent basis for the body of the claim; or (iii) it was clearly relied upon during prosecution "to distinguish the claimed invention from the prior art." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-09 (Fed. Cir. 2002). None of these exceptions apply here. Therefore, the preamble does not limit the scope of claim 18.

First, the preamble does not recite "essential structure or . . . give life, meaning, and vitality" to the formulation claimed in the body of claim 18. The Federal Circuit has explained that a preamble does not "give 'life, meaning, and vitality' to the claim" and is therefore "not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Catalina*, 289 F.3d at 808-10. This is precisely the case here. The body of claim 18 describes a structurally complete

formulation of dextromethorphan and quinidine. This is demonstrated by the simple fact that if the preamble were deleted, the claimed formulation itself would not change. *See, e.g., Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1295 (Fed. Cir. 2004) (If the body of the claim "describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention . . . the preamble is generally not limiting.").

Moreover, Defendants ***admit*** that the preamble merely expresses an ***intended*** purpose of the claim. Their construction explicitly states: "A unit dosage formulation ***intended*** to treat chronic or intractable pain." (emphasis added). This type of "intended use" preamble is not a proper claim limitation. *See Catalina*, 289 F.3d at 808 ("preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure"); *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 1347-48 (Fed. Cir. 2000) (affirming the district court's finding that the preamble was not a claim limitation where it "simply describe[d] the purpose of the claimed method"). Accordingly, the "essential structure … life, meaning, and vitality" exception does not render claim 18's preamble a limitation.

Next, the body of claim 18 does not rely upon or derive antecedent basis from the preamble. *Catalina*, 289 F.3d at 808; *American Med. Sys.*, 618 F.3d at 1359 (claim's preamble did not provide antecedent basis, thus was not a limitation, where it did not provide "context essential to understanding the meaning of any of the terms in the body"). This is evident from the claim language itself. Defendants have not identified any evidence to the contrary. Thus, the "antecedent basis" exception does not apply.

Finally, the patentees never relied upon the preamble language of claim 18 to distinguish prior art during prosecution of the '115 patent. *See Symantec Corp. v. Computer Assocs. Int'l,*

Inc., 522 F.3d 1279, 1289 (Fed. Cir. 2008) (finding the preamble was not a claim limitation where the prosecution history "fail[ed] to demonstrate 'clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art'") (quoting *Catalina*, 289 F.3d at 808). Again, Defendants have not identified any evidence to the contrary. Thus, the "distinguishing prior art" exception also does not render claim 18's preamble a limitation.

For the above reasons, the preamble of claim 18 is not a claim limitation. Thus, it need not be construed.

2. "a debrisoquin hydroxylase inhibitor"

Avanir's Construction	**Defendants' Construction**
A cytochrome P-450 2D6 inhibitor, excluding cimetidine	A compound capable of inhibiting the oxidation of dextromethorphan by the liver enzyme debrisoquin hydroxylase

The parties agree that "a debrisoquin hydroxylase inhibitor" requires construction. The parties' proposed constructions are substantially similar[2], with one significant exception: Avanir has properly excluded the drug cimetidine from the scope of the term.

The doctrine of prosecution disclaimer is "a fundamental precept [of] claim construction jurisprudence" that precludes a claim from covering "specific meanings disclaimed during prosecution." *Omega Eng'g v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). To operate as a disclaimer, a statement in the prosecution history must be "clear and unmistakable." *Id.* at 1325-26. Additionally, a prosecution disclaimer made in an ancestor application will attach with equal force to that same limitation in any subsequent patent claims. *Id.* at 1333.

[2] The specification explains that the enzyme "debrisoquin hyrdroxlyase" is "also known as … cytochrome P-450 2D6." (Ex. A, 3:51-55.) Thus, "a compound capable of inhibiting the oxidation … by the liver enzyme debrisoquin hydroxylase" is just another way of saying "a cytochrome P-450 2D6 inhibitor." To the extent that Defendants argue otherwise, Avanir reserves the right to rebut any such argument in its opposition brief.

Here, during the prosecution of U.S. Patent No. 5,863,927, which reissued as the '115 patent, the patentee made such a clear and unmistakable disclaimer. In response to a rejection from the Patent Office over prior art, the patentee specifically excluded one particular drug—cimetidine—from the possible debrisoquin hydroxylase inhibitors that could fall within the scope of the patent's claims, stating:

> In reply, all references to cimetidine as an debrisoquin hydroxylase inhibitor have been deleted. Cimetidine is not known or recognized as an effective inhibitor of debrisoquin hydroxylase, and it should not have been included in the list of inhibitors.

(Ex. C, August 11, 1997 response to PTO office action, at AVAN-002145.) The patentee's statement provides a textbook example of prosecution disclaimer. *Omega*, 334 F.3d at 1324 ("where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender"). Based on this unequivocal limiting definition, the term "a debrisoquin hydroxylase inhibitor" in claim 18 cannot properly be construed to encompass cimetidine.

Defendants' proposed construction improperly ignores this clear and unmistakable disavowal of cimetidine. Thus, this Court should adopt Avanir's proposed construction, which properly reflects the limiting definition discussed above.

3. "chronic pain"

Avanir's Construction	**Defendants' Construction**
Long-term pain, i.e., pain lasting three months or longer	Long-term pain resulting from conditions such as stroke, cancer and trauma, as well as neuropathic pain due to deterioration of nerve tissue such as postherpetic neuralgia (PHN) resulting from herpes zoster infection, and diabetic neuropathy resulting from long-time diabetes

The parties agree that "chronic pain" requires construction. The parties further agree that the patentee explicitly defined "chronic pain" in part as "long term pain." (Ex. A at 2:34-35.) The dispute regarding this claim term concerns the remainder of the parties' proposed constructions.

A person of ordinary skill in the art would understand that "chronic pain" or "long-term pain" means pain lasting three months or longer. Accordingly, for the sake of completeness and clarity, Avanir has added this well-understood threshold to its proposed construction of "chronic pain." Indeed, multitudes of scientific references reflecting the knowledge of the ordinary-skilled artisan confirm Avanir's proposed construction. For example, in 1986, the International Association for the Study of Pain ("IASP"), a leading professional forum in its field, recognized that "chronic pain ha[d] gradually emerged as a distinct phenomenon in comparison with acute pain" and "[took] three months as the most convenient point of division between acute and chronic pain." (Ex. D, ISAP, *Classification of Chronic Pain*, PAIN, Suppl. 3:S1, S5 (1986).) Over the ensuing decades, technical publications have repeatedly adopted the IASP's three month period as the threshold for defining chronic pain.[3]

In contrast, Defendants' proposed construction does not provide any guidance on the meaning of "long-term pain." Instead, the remainder of Defendants' construction is a non-

[3] *See, e.g.*, Ex. E, V. Wylde, et al., *The Effect of Local Anesthetic Wound Infiltration on Chronic Pain After Lower Limb Joint Replacement: A Protocol for a Double-Blind Randomised Controlled Trial*, BMC MUSCULOSKELETAL DISORDERS, 12:53, 54 (2011) ("Chronic pain after surgery is . . . of at least 3-months duration."); Ex. F, J.M. Manubay et al., *Prescription Drug Abuse: Epidemiology, Regulatory Issues, Chronic Pain Management with Narcotic Analgesics*, PRIM. CARE, 38(1):71, 78 (2011) ("The definition of chronic pain is pain that persists beyond normal tissue healing time, which is assumed to be three months."); Ex. G, S. Aroori & A.J. Spence, *Chronic Pain After Hernia Surgery – An Informed Consent Issue*, ULSTER MED J, 76(3):136, 136 (2007) ("Chronic pain was defined as pain persisting beyond the normal tissue healing time: 3 months."); Ex. H, F. Vonk, et al., *Effectiveness of Behavioural Graded Activity compared with Physiotherapy Treatment in Chronic Neck Pain: Design of a Randomised Clinical Trial* [ISRCTN88733332], BMC MUSCULOSKELETAL DISORDERS, 5:34, 35 (2004) ("When neck pain persists for more than 3 months it is defined as chronic ….").

exclusive list of examples of conditions that ***may cause*** "chronic pain." *See* D.I. 110 at 5-6 (reciting chronic pain can be "***resulting from conditions such as*** stroke, cancer and trauma, as well as neuropathic pain due to deterioration of nerve tissue such as postherpetic neuralgia (PHN) resulting from herpes zoster infection, and diabetic neuropathy resulting from long-time diabetes") (emphasis added). The use of the words "such as" alert the reader that what follows are representative examples only. This non-exclusive list of examples, however, does not provide any definition as to the meaning of chronic pain to assist the trier of fact. Moreover, examples are not proper claim limitations. *See Phillips*, 415 F.3d at 1323 (noting "the danger of reading limitations from the specification into the claim"); *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification."). Thus, this Court should reject Defendants' overly-limiting construction, and adopt Avanir's proposed construction.

4. "intractable pain"

Avanir's Construction	**Defendants' Construction**
Pain that will not respond adequately to conventional medications	Pain which failed to respond to other treatments

The parties agree that "intractable pain" requires construction. The parties' constructions are similar, but Avanir's construction is more closely aligned with the specification and the term's plain and ordinary meaning.

Avanir's construction comes from the specification. There, the patentee explicitly defined the term "intractable" in the context of "intractable" coughing as "coughing that will not respond adequately to non-addictive, non-steroid medications." (Ex. A, at 2:26-28.) The

specification also indicates that non-addictive, non-steroid medications are conventional medications used in the treatment of cough:

> A number of chronic disorders have symptoms which are known to be very difficult to treat, and often fail to respond to safe, non-addictive, and non-steroid medications. ***Such disorders, such as intractable coughing, fail to respond to conventional medicines*** and must be treated by such drugs as codeine, morphine, or the anti-inflammatory steroid prednisone. These drugs are unacceptable for long-term treatment due to dangerous side-effects, long-term risks to the patient's health, or the danger of addiction.

(Ex. A, at 1:23-32.) Avanir's proposed construction, therefore, derives directly from the specification.

Defendants' construction, by contrast, comes not from an explicit definition from the specification, but instead from a random line in the specification. The patentee stated: "the present invention provides compositions for use in the preparation of medicaments for the effective treatment of a variety of chronic and intractable disorders which failed to respond to other treatments." (Ex. A at 2:44-47.)[4] Nothing about this statement indicates that it is meant to be a definition of "intractable pain." Thus, Defendants' definition reads out the qualifiers that intractable pain fails to respond *adequately* to *conventional* treatments.

5. "a combined dosage which renders the dextromethorphan therapeutically effective in substantially reducing chronic or intractable pain without causing unacceptable side effects"

The parties also have a dispute regarding whether this phrase as a whole needs construction, as follows:

[4] Defendants' remaining citations to the specification are even further removed from providing anything resembling a definition for "intractable pain."

Avanir's Construction	**Defendants' Construction**
This is not a single claim term and is not amenable to construction; instead, it should be construed by reference to the individual claim terms contained therein: (1) "a combined dosage;" (2) "which renders;" (3) "the dextromethorphan;" (4) "therapeutically effective," (5) "in," (6) "substantially reducing," (7) "chronic pain," (8) "intractable pain," and (9) "without causing unacceptable side effects." Avanir asserts that except for "chronic pain" and "intractable pain" (as defined above), each of these terms needs no construction and has its ordinary meaning.	About 20 mg/day to about 200 mg/day of dextromethorphan or salt thereof and 50 mg/day to 300 mg/day of the debrisoquin hydroxylase inhibitor (DHI) quinidine for treatment of chronic or intractable pain. Dosages of other DHIs will vary with the DHI, and should be determined on an individual basis using the protocol described in Example 4. To the extent Defendants' construction is not adopted and "substantially reducing chronic or intractable pain" needs further construction, it is indefinite and/or does not otherwise satisfy the requirements of 35 U.S.C. § 112. To the extent Defendants' construction is not adopted and "without causing unacceptable side effects" needs further construction, it is indefinite and/or does not otherwise satisfy the requirements of 35 U.S.C. § 112.

Defendants insist this 21-word phrase must be construed as a whole, but have no support in the intrinsic evidence that the patentee intended any special meaning for this phrase. Most importantly, at no place in the patent specification is this phrase as a whole specially defined, or even used. Thus, the patentees did not act as their own lexicographer with respect to this phrase.

Indeed, aside from chronic or intractable pain (discussed above), the patentee has not explicitly defined ***any*** of the remaining claim terms in this phrase. When the patentee has not provided an explicit definition of a claim term, the words of a claim are given the full scope of their plain and ordinary meaning. *See Vitronics*, 90 F.3d at 1582. Since the remaining claim terms have well-understood meanings, it is not necessary for the Court to construe those terms — lest courts be inundated with requests to parse the meaning of every word in the asserted claims. *Pfizer, Inc. v. Dr. Reddy's Labs., Inc.*, No. 09-cv-943, 2011 WL 767849, at *6 (D. Del. Feb. 28,

2011) (Stark, J.) ("the claim construction process should not become 'an obligatory exercise in redundancy'") (citation omitted).

While Defendants have proffered constructions for "chronic pain" and "intractable pain," they have refused to take a position on whether the remaining claim terms carry their plain or ordinary meaning, or whether they carry some other meaning heretofore known only to Defendants. Indeed, during the meet-and-confers leading up to the submission of the Joint Claim Construction Chart, counsel for Avanir repeatedly asked counsel for Defendants to explain whether they believed any of the remaining words had any meaning other than the plain and ordinary meaning of the words. Defendants refused to even answer the questions:

Term	Avanir's Construction	Defendants' Construction
"a combined dosage"	Plain and ordinary meaning	???
"which renders"	Plain and ordinary meaning	???
"the dextromethorphan"	Plain and ordinary meaning	???
"therapeutically effective"	Plain and ordinary meaning	???
"in"	Plain and ordinary meaning	???
"substantially reducing"	Plain and ordinary meaning	???
"chronic pain"	Discussed above	Discussed above
"intractable pain"	Discussed above	Discussed above
"without causing unacceptable side effects"	Plain and ordinary meaning	???

(*See* Ex. I, Avanir's July 19, 2012 proposed Joint Claim Construction Chart, at p. 7; Ex. J, Defendants' July 20, 2012 proposed Joint Claim Construction Chart, at p. 14.) Defendants' refusal to even discuss the meaning for these terms should be deemed a waiver, precluding Defendants from subsequently offering any competing constructions for these terms or arguing that these terms need construction.

Defendants' failure to offer competing constructions of these claim terms is not surprising, as doing so would expose the fact that Defendants simply ignore certain terms at the

expense of others by construing the phrase as whole. Yet Defendants have not identified anything in the claim language or other intrinsic evidence that overcomes the heavy burden against abandoning the plain and ordinary meaning of the remaining terms contained in this phrase. *See Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007). Since Defendants' construction is neither the patentee's lexicography nor the plain and ordinary meaning of the words themselves, it should be rejected.

Moreover, even if it were proper to construe this phrase as a whole, Defendants' proposed construction provides a textbook example of improperly importing limitations from the specification into the claim. *See Phillips*, 415 F.3d at 1323 (noting "the danger of reading limitations from the specification into the claim"); *Tex. Instruments*, 805 F.2d at 1563 ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific example sin the specification."). The numeric limitations in Defendants' proposed construction appear nowhere in the claim itself. Rather, they are specific embodiments disclosed in the '115 patent's specification. These types of specific embodiments are not proper claim limitations.[5] Thus, Defendants' construction lacks merit, both for improperly joining multiple claim terms into a single phrase and for attempting to read nonexistent limitations into the claims. The Court should reject Defendants' proposal and adopt Avanir's construction.[6]

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[5] *See, e.g., Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1358 (Fed. Cir. 2006) (affirming construction of "water-alcohol mixture" by refusing to limit the term to the specification's disclosure of mixtures containing at least 30 percent water); *Abbott Labs. v. Baxter Pharms. Prods., Inc.*, 334 F.3d 1274, 1279-80 (Fed. Cir. 2003) (declining to construe the term "effective amount" as limited to "ranges from about 0.0150% w/w [] to 0.14% w/w" disclosed in the specification); *Honeywell Int'l, Inc. v. Nikon Corp.*, 589 F.Supp.2d 433, 450-51 (D. Del. 2008) (construing term "slight misalignment" as not strictly limited to the specification's disclosure of specific rotational misalignments of 2-16 degrees).

[6] To the extent that the Court finds that construction of the entire phrase is necessary, Avanir proposes that the meaning is the sum of the individual claim terms.

B. The '282 Patent

The parties' disagreements regarding the '282 patent are minor and appear to be largely semantic in nature. The '282 patent is titled "Pharmaceutical Compositions Comprising Dextromethorphan And Quinidine For The Treatment Of Neurological Disorders" and concerns methods of treating the neurological disorders, pseudobulbar affect and emotional lability. These neurological disorders occur secondary to other neurological diseases and injuries such as amyotrophic lateral sclerosis (ALS), often referred to as "Lou Gehrig's Disease," multiple sclerosis, Alzheimer's disease, stroke and traumatic brain injury. The person of ordinary skill in the art with respect to the '282 patent would be a medical professional, such as a neurologist or psychiatrist, skilled in the treatment of the underlying neurological diseases and injuries. (Ex. B at 1:24-37.)

Claim 1 states (with emphasis on the disputed claim terms):

> **A method for treating pseudobulbar affect or emotional lability**, the method comprising administering to a patient in need thereof **dextromethorphan in combination with quinidine**, wherein the amount of dextromethorphan administered comprises from about 20 mg/day to about 80 mg/day and wherein the amount of quinidine administered comprises from about 10 mg/day to less than about 30 mg/day with the proviso that the weight to weight ratio of dextromethorphan to quinidine is 1:0.5 or less.

1. "A method for treating pseudobulbar affect or emotional lability"

Avanir's Construction	Defendants' Construction
A method for treating ***a neurological disorder*** characterized by intermittent spasmodic outbursts of emotion at inappropriate times or in the absence of any particular provocation	A method for treating ***the condition known as pseudobulbar affect or emotional lability (also referred to by the terms emotionalism, emotional incontinence, emotional discontrol, excessive emotionalism, and pathological laughing and crying), which is*** characterized by intermittent spasmodic emotional outbursts at inappropriate times or in the absence of any particular provocation.

"A method for treating pseudobulbar affect or emotional lability" is the preamble of claim 1 of the '282 patent. For this claim, the parties agree that the preamble is a limitation. As discussed above, a claim's preamble "generally is not limiting" absent a specific exception, such as "clear reliance on the preamble in the prosecution history, or in situations where it is necessary to provide antecedent basis for the body of the claim." *Symantec*, 522 F.3d at 1288. Here, the preamble provides necessary antecedent basis for claim 2. Specifically, claim 2 recites:

> "The method of claim 1, wherein ***the pseudobulbar affect or emotional lability*** is caused by . . ."

The language in claim 2, "***the*** pseudobulbar affect or emotional lability" would lack antecedent basis without the preamble "a method for treating pseudobulbar affect or emotional lability." Accordingly, the preamble is necessarily a limitation.

The parties also largely agree on the construction of this claim term. The parties agree that "pseudobulbar affect" and "emotional lability" are "characterized by intermittent spasmodic emotional outbursts at inappropriate times or in the absence of any particular provocation."

The only dispute regarding this term concerns the identification of what is being treated. Avanir proposes the language "a method for treating ***a neurological disorder*** . . . ." The language "a neurological disorder" is taken directly from the specification:

FIELD OF THE INVENTION

> Pharmaceutical compositions and methods for ***treating neurological disorders*** are provided. The compositions comprise dextromethorphan in combination with quinidine.

(Ex. B at 1:15-20) (emphasis added.) Similarly, the title of the patent itself states:

> Pharmaceutical Compositions Comprising Dextromethorphan And Quinidine For The Treatment Of ***Neurological Disorders***

(*Id.* at title) (emphasis added). Thus, "pseudobulbar affect" and "emotional lability" are neurological disorders.

In contrast, Defendants propose the language "a method for treating ***the condition known as pseudobulbar affect or emotional lability*** . . . ." First, Defendants are defining the term with the term — it does not make sense to construe "pseudobulbar affect or emotional lability" with the words "pseudobulbar affect or emotional lability." Simply parroting back the words of the term does not help the finder of fact. Second, Defendants include a parenthetical stating that pseudobulbar affect or emotional lability are:

> (also referred to by the terms emotionalism, emotional incontinence, emotional discontrol, excessive emotionalism, and pathological laughing and crying).

These are, at best, other names that have been used to describe the neurological disorders at issue. They are not, however, definitions of the term. Indeed, by setting them off in parentheses, Defendants are indicating that these other names are not part of their construction. Accordingly, they should not be included, and Avanir's construction should be adopted.

2. "dextromethorphan in combination with quinidine"

Avanir's Construction	**Defendants' Construction**
Dextromethorphan and quinidine given in a combined dose, or in separate doses administered substantially simultaneously	Dextromethorphan and quinidine co-administered in combined doses or separate doses

The sole issue concerning this term is the meaning of "in combination." The '282 patent does not provide an explicit lexicography for this term. Accordingly, the Federal Circuit directs the Court to look to the meaning of the term in the context of the claims and specification. *See Phillips*, 415 F.3d at 1313 (claim terms are to be read "not only in the context of the particular

claim in which the disputed term appears, but in the context of the entire patent, including the specification.")

Here, the parties agree that the '282 patent contemplates administration of dextromethorphan "in combination" with quinidine both as combined doses (e.g., dextromethorphan and the quinidine in the same capsule) and as separate doses (e.g., dextromethorphan and quinidine in separate capsules). (*See* Ex. B at claims 3 and 12.) The dispute concerns only the latter half of this — what it means to administer dextromethorphan "in combination with" quinidine when they are in ***separate doses***. Here, the specification of the '282 patent addresses that exact question. First, separate doses "in combination" can mean that the two capsules are taken at the exact same time:

> It may also be preferred to administer the combined dose (or ***separate doses simultaneously administered***) . . . .

(*Id.* at 15:39-41.) Second, the specification teaches that the separate doses can be administered at *almost* the exact same time:

> [I]t is preferred to administer the dextromethorphan and quinidine in a combined dose, or in ***separate doses administered substantially simultaneously***.

(*Id.* at 15:20-22.) Thus, the specification supports Avanir's construction of "dextromethorphan in combination with quinidine" as "dextromethorphan and quinidine given in a combined dose, or in separate doses administered substantially simultaneously."

This is also common sense. In order for two separate doses to be "in combination," they must have a temporal link. If there were no link — for example, if a patient took dextromethorphan on Monday and quinidine the following Friday — then two doses would not be "in combination." Indeed, this would defeat the purpose of the invention. Here, Avanir's

proposed construction uses the broadest temporal link set forth in the specification — "substantially simultaneously."

In contrast, Defendants have not included a temporal link between the separate doses in their construction. Instead, Defendants have included the word "co-administered." While "co-administer" is used in the specification, it is not used in conjunction with "separate doses" and the specification provides no guidance as to its meaning. Accordingly, the Court should adopt Avanir's proposed construction.

VI. CONCLUSION

For the foregoing reasons, Avanir respectfully requests that the Court adopt its proposed constructions of the disputed claim terms.

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August 17, 2012

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2012, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 17, 2012, upon the following in the manner indicated:

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